# EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W. SUITE 600 WASHINGTON, D.C. 20036

> PHONE: (202) 466-6937 Fax: (202) 466-6938 E-MAIL: WWW.EMORD.COM



February 12, 1998

### VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343(r)

Dear Dr. Yetley:

Maitake Products, Inc., by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Maitake Products, Inc. retains scientific documentation supporting the statements.

# 1. Supplement Brand Name

Prost-Mate

### Supplement Ingredient

Beta-glucan Lycopene Green Tea Pumpkin Seed Maitake Mushroom

# Text of Statements of Nutritional Support

A dynamite formula that helps maintain a healthy prostate.

LET1411 51119

<sup>&</sup>lt;sup>1</sup> The address for Maitake Products, Inc., 222 Bergen Tpk., 1<sup>st</sup> Floor East, Ridgefield Park, New Jersey 07660.

Maitake D-fraction is our potent extract of the Japanese mushroom Grifola frondosa shown in scientific research to enhance immune function.

Maitake D-fraction is a standardized form of Beta-glucan extracted from Maitake Mushrooms (Grifola frondosa), known as an active constituent that provides nutritional support for cellular immune function.

This product also contains Lycopene, Green Tea Extract and Pumpkin Seed dried powder, all known to help maintain healthy prostate.

#### 2. Supplement Brand Name

Maitake Mushroom Extract

#### **Supplement Ingredients**

Maitake Mushroom Polysaccharide Beta-glucan

#### Text of Statements of Nutritional Support

Our D-fraction is a potent extract of a protein-based polysaccharide of the Maitake mushroom (Grifola frondosa) known as beta 1,6 glucan, 1,3 glucan, shown in scientific research studies to enhance immune function.

Scientific studies have shown that this potent extract enhances immune system function.

Modern science has identified in Maitake a polysaccharide compound; Beta-glucan as an active constituent to stimulate cellular immune activity.

This product provides nutritional support for healthy immune system function.

A polysaccharide compound contained in Maitake, called Beta-glucan, is known to help build up the immune system.

Also, studies indicate that Maitake provides important nutritional support for the healthy functioning of the heart and circulatory systems.

#### 3. Supplement Brand Name

Maitake Products, Inc., Advertisement

Maitake, Prostmate, D-fraction, Mai Green Tea

#### Text of Statements of Nutritional Support

D-fraction is a standardized extract of active constituent beta 1,6 glucan, 1,3 glucan, which has been shown in scientific studies to enhance immune activity.

Mai Green Tea is excellent as an antioxidant and immune booster.

#### 4. Supplement Brand Name

Maitake Mushroom Extract (alcohol free)

### **Supplement Ingredients**

Maitake Mushroom Beta-glucan

# Text of Statements of Nutritional Support

Modern science has found Beta-glucan in Maitake the active ingredient that provides nutritional support for cellular immune function.

This product provides nutritional support for immune system function, and may not be used as an adaptogen.

In accordance with 21 USC 343(r)(6) and 21 CFR § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in bold (and in a box): "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Respectfully submitted,

Jonathan W. Emord

Claudia A. Lewis-Eng

#### Certification

I. Michael Shirota, President of Maitake Products, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Maitake Products, Inc., has substantiation that the statements of nutritional support contained in the attached notice are truthful and non-misleading.

Executed on: Feb 11 98

Michael Shirota